Fred Thompson, III



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May 10, 2013

Via Facsimile 914-390-4278

Honorable Cathy Seibel United States District Judge Southern District of New York Hon. Charles L. Brieant Jr. Federal Building and United States Courthouse 300 Quarropas St. White Plains, NY 10601-4150

Re: In re Mirena IUD Product Liability Litigation

No. 13-MD-2434 (CS)

Dear Judge Seibel:

Please find attached Plaintiff's Position Statement and a spreadsheet listing all Related Cases pursuant to Order No. 1. By copy of this letter, we are copying counsel for Defendant with same.

Please do not hesitate to contact us should you have any questions. With kindest regards, I am

Very truly yours,

Proposed Co-Lead Counsel

ANAPOL SCHWARTZ

/s/ James R. Ronca

James R. Ronca

MOTLEY RICE LLC

Fred Thompson, III

PARKER WAICHMAN LLP

/s/ Matthew McCauley

Matthew McCauley

SEEGER WEISS LLP

/s/ Diogenes P. Kekatos

Diogenes P. Kekatos

Enclosures

CC:

James Shepherd, Esq. (via e-mail) Marie S. Woodbury, Esq. (via e-mail) Shayna Cook, Esq. (via e-mail) All Plaintiff Counsel (via e-mail)

MT. PLEASANT, SC | PROVIDENCE, RI | HARTFORD, CT | NEW YORK, NY MORGANTOWN, WY | WASHINGTON, DC | LOS ANGELES, CA | NEW ORLEANS, LA

Motley Rice LLP operates the California office.

05/10/2013 16:39 8432169440 MOTLEY RICE LLC PAGE 03/20 Case 7:13-md-02434-CS-LMS Document 77 Filed 05/13/13 Page 2 of 20

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK	
IN RE: MIRENA IUD PRODUCTS LIABILITY LITIGATION MDL 2434	PLAINTIFFS' POSITION STATEMENT
This Document Relates to All Actions	

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Mirena is an intrauterine contraceptive system ("IUS") currently manufactured and sold by Bayer Healthcare Pharmaceuticals, Inc., ("Bayer"). Mirena is designed to achieve contraception by interacting with the uterine environment and emitting a progestin into the uterus for a period of five years, after which Bayer does not guarantee its efficacy. Bayer promotes the product as being safe and effective, as well as easily removable by a physician at any time users choose, purportedly allowing a quick return to fertility. Mirena was approved as a drug, not a device, under section 505(b) of the Food, Drug and Cosmetic Act because of the Levonorgestrel ("LNG"), a synthetic progestogen, it emits from the IUS reservoir. As such, Mirena did not undergo premarket approval or 510k approval.

Mirena is placed in the uterus by a physician, or other healthcare provider such as a nurse midwife or nurse practitioner, with the use of an insertion tool provided by the manufacturer.

Once Mirena is placed, the inserter is discarded. Two threads attached to the stem of Mirena serve the purpose of helping determine whether Mirena is situated properly within the uterus and assist in vaginal removal of the IUS. Mirena's package information states that Mirena may be removed at any time by "applying gentle traction on the threads with forceps"

Mirena is intended to provide an initial release rate of 20 µg/day of LNG. Over the course of the five years in which Mirena is intended to remain placed, the LNG gradually

¹ The instant Position Statement was prepared by the Proposed Lead Counsel but circulated to all interested Plaintiffs' counsel for review and comment.

decreases to an amount of approximately half of the original daily release amount. According to the manufacturer, it is unclear how pregnancy is prevented by Mirena, but the prescribing information suggests several mechanisms: "thickening of cervical mucus preventing passage of sperm into the uterus, inhibition of sperm capacitation or survival, and alteration of the endometrium." The packaging information states that "Mirena is recommended for women who have had at least one child" without further explanation.



Figure 1: Mirena consists of a T-shaped polyethylene frame measuring 32 mm by 32 mm with a steroid reservoir around a vertical stem. A monofilament string attaches to the vertical stem. The reservoir contains 52 mg of levonorgestrel.

Plaintiffs in this litigation claim that the Defendant failed to warn them of the potential for serious injury associated with normal use of Mirena—specifically, spontaneous migration after proper insertion and subsequent embedment in or perforation of the uterus, or other injuries related to the migration. Each Plaintiff claims to have experienced a successful Mirena insertion without any indication of physician error or complication that could lead to uterine perforation or other injury related to insertion. Plaintiffs also claim objective evidence of appropriate placement of Mirena within the uterine cavity, either by Mirena string check, ultrasound, x-ray, or physician confirmation. Finally, each Plaintiff claims an injury related to the subsequent finding that Mirena embedded into, migrated, and/or perforated the uterine liming, requiring surgical removal. In many other actions, Mirena has migrated towards vital organs and exploratory surgery revealed that removal could further seriously endanger the plaintiff's health. In those cases, future diagnostic surveillance is required. Plaintiffs claim that the design of

Mirena contributes to the IUS's ability to spontaneously embed into, migrate and/or perforate the uterus.

The Mirena label has undergone a number of changes since its introduction in 2001 but as will be established by the plaintiffs, the changes fail to fully advise users of known risks associated with the product. The initial, or "launch," label contained a very limited warning in the "Perforations" section that read:

An IUD may perforate the uterus or cervix, most-often during insertion although the perforation may not be detected until some time later.

(Emphasis added.) In April 2008, Bayer changed the "Perforations" section of the label to read as follows:

An IUD may perforate the uterus or cervix, most often during insertion although the perforation may not be detected until some time later. . . . Delayed detection of perforation may result in migration outside the uterine cavity, . . .

(Emphasis added.) In July 2008, the Mirena label "Perforations" section changed again, this time with Bayer removing "most often" from the language:

Perforation or penetration of the uterine wall or cervix may occur during insertion although the perforation may not be detected until some time later.... Delayed detection of perforation may result in migration outside the uterine cavity, ...

(Emphasis added.) The "Highlights of Prescribing Information," located on the first page of the Mirena package label, was revised in October 2009, and added language to the Warnings and Precautions Section: "Perforation may occur during insertion. Risk is increased in women with fixed retroverted uteri, during lactation, and postpartum." The Precautions Section in the label itself remains unchanged from July 2008.

06/20

At no time since the introduction of Mirena to the market has the label, prescribing information, or patient information included any indication that spontaneous perforation may occur with use of the product.

Bayer did, however, increase its marketing effort to "busy moms" and others that failed to provide adequate warnings about the known risks of spontaneous migration of Mirena. On March 26, 2009, Bayer was cited by the Food and Drug Administration (FDA) because of Bayer's material misrepresentations and omissions regarding the efficacy of Mirena without providing "any" risk information. Less than nine months later, in December 2009, the FDA again issued a Warning Letter to Bayer for its "Mirena Simple Style Statements Program." The Bayer promotion targeted "busy moms" and misrepresented Mirena as a contraceptive that would purportedly increase intimacy, sexual spontaneity, and increased libido. Among other issues, this questionable promotional program failed to disclose many risks associated with Mirena use. In both instances, the Division of Drug Marketing, Advertising and Communications ("DDMAC") requested that Bayer immediately cease dissemination of the misleading promotional materials. As will be established, many plaintiffs specifically requested this contraceptive product over others because of Bayer's aggressive direct-to-consumer marketing efforts.

In June of 2010, Bayer and Health Canada issued a joint safety statement stating that women in the US and Canada reported injuries related to use of Mirena. Specifically the statement said:

Uterine perforation is a rare, but serious complication associated with intrauterine contraceptive devices, and occurs at a rate between 1/1,000 and 1/10,000 insertions. Bayer Inc. continues to receive post-market reports of uterine perforation associated with the use of MIRENA®. Some cases of uterine perforation were not detected during or immediately after the insertion. The risk of perforation may be increased with use in the post-partum period, during lactation, and in women with an atypical uterine anatomy

(such as fixed retroverted uterus). Uterine perforation may occur with MIRENA® at the time of insertion or after the insertion with limited clinical symptoms.

07/20

The first known Mirena case was filed in January 2011 and was transferred to the MDL from the U.S. District Court for the District of South Carolina, Florence Division. (Kelli and Justin Baugh v. Bayer Health Care Pharmaceuticals, No. 4:11-cv-00525). While the Baugh case is procedurally more advanced than other filed Mirena actions, the discovery conducted in that matter suffers from limitations of the period during which Ms. Baugh was exposed to Mirena. Minimal documents were also produced in Osborne v. Bayer Corporation, No. 5:11-cv-00421, and are similarly limited. With the exception of less than 125,000 documents produced by the Defendants in these two cases, consisting primarily of the New Drug Application ("NDA") and the Investigational New Drug Application ("IND"), and comprised of custodial files of only six individuals, no discovery has been undertaken in any other MDL action. This extremely limited document production in these cases is merely a starting point and not nearly what is required for the thousands of cases expected to be filed in this MDL. Since the production of the custodial files, Plaintiffs have discovered that the defense-suggested custodians are not appropriate for the entire time period covering each Plaintiff's claim. Further, these documents were produced under an expedited discovery schedule where Plaintiff's counsel had more limited resources than available in an MDL. Additionally, Plaintiffs contend the document productions are incomplete and will necessitate additional discovery and additional production of documents, likely to be voluminous.

Attached to this Position Statement is a list of all related cases pending in state or federal court, providing the status for each.

05/10/2013 16:39 8432169440 MOTLEY RICE LLC PAGE 08/20

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JAYME L. BUCHER and BRANDON BUCHER	JESSICA MARIE THOMAS and ROWDY THOMAS	JENNIFER RENEE SIMON and RYAN DALE SIMON	SHAREE MARK CHU SCHWANTZ and CHARLES MACON THOMAS SCHWANTZ	PATRICIA REID and SAMUEL B. REID	ANGELA GAYLE OAKLEY and B. KEITH OAKLEY	ASHLEIGH NICOLE HALL and CRAIG L. HALL	SUZI GLUCK	KIMBERLY D. ELLIOTT	MICHELE LEE FOWLER and DAVID F. FOWLER	SAMANTHA ANN BARNETT	CARRIE ELIZABETH MADDEN	JOY VIOLA HOLT	SAMANTHA LYNN DEMASTUS	KELSIE DENTON	DONNA SHATTO	CONSENTHIA EDMISTON
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KATELIN S. LEE	MARIE CANTELLI and PETER EDWARD CANTELLI	BRITTANY PIAZZA	LATOYA L. SCOTT	NATASHIA L. SNYDER	KATARINA A. SIMPSON	ERNESTINE AYISSI	SAMANTHA LEIGH JASKIEL	DEDRA MEEKINS	SHOSHANA BLOCH	KRISTY OLSON	SHI MUNOZ	BARBARA WHILHITE and JASON L. WILHITE	KALA NUGENT	NICHOLA ELAINE DOTSON and DEVON DASHAUN DOTSON	REYANNE BRUMLEY	RHONDA LYNNE ARRINGTON and BRIAN J. ARRINGTON	LEA MARIE GOMEZ	JESSICA HAMMETT and DREW HAMMETT
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05/10/2013 16:39 8432169440 MOTLEY RICE LLC PAGE 17/20 Case 7:13-md-02434-CS-LMS Document 77 Filed 05/13/13 Page 16 of 20

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N/A	N/A	N/A	N/A	N/A	N/A		N/A	N/A		N/A		N/A	N/A		N/A		N/A	N/A	ıv/a	N/A	•	N/A	M /A	n/n	N /A	17/11	N/A		N/A		N/A
Pending Decision of Motion for Coordination	Pending Decision of Motion	Pending Decision of Motion	for Coordination	Pending Decision of Motion	Pending Decision of Motion	for Coordination	Pending Decision of Motion	ior coordination	Pending Decision of Motion for Coordination	Pending Decision of Motion	for Coordination	Pending Decision of Motion	for Coordination	Pending Decision of Motion	Donding Design of Moston	for Coordination	Pending Decision of Motion	for Coordination	Pending Decision of Motion	Panding Design of Metics	for County Deceased of Monaco	Pending Decision of Motion	for Coordination	Pending Decision of Motion	for Coordination	Pending Decision of Motion		Pending Decision of Motion for Coordination			
N.J. Sup. Ct. Morris Cty.	N.J. Sup. Ct. Morris Ctv.	N.J. Sup. Ct., Morris Ctv.	N.J. Sup. Ct., Morris Ctv.	N.J. Sup. Ct., Morris Ct.	N.J. Sup. Ct.,	Morris Cty.	N.J. Sup. Ct. Morris Ctv.	N.J. Sup. Ct.	Morris Cty.	N.J. Sup. Ct.	MOLTES CLY.	N.J. Sup. Ct., Morris Cty.	N.J. Sup. Ct.	MOTHS CTY.	N.J. Sup. Ct.	Morris Cty.	N.J. Sup. Ct., Morris Chr.	NI Sun Ct	Morris Cty.	N.J. Sup. Ct.,	Morris Cty.	N.J. Sup. Ct.	NI Sun C	Marrie Ct.	N. Sun Cr	Morris Cty	N.J. Sup. Ct.,	Morris Cty.	N.J. Sup. Ct.	Morris Cty.	N.J. Sup. Ct. Morris Cty.
MRS-L-0592-13	MRS-L-0591-13	MRS-L-0579-13	MRS-L-0561-13	MRS - L - 0560-13	MRS-L-0553-13	A CHARLE A COLLEGE	MKS - L - 0552-13	MRS - L - 0551-13		MRS-L-0550-13	1400 T 0710	MKS - L - 0549-13	MRS-L-0548-13		MRS - L - 0491-13		MRS-L-0488-13	MRS - 1, - 0487-13		MRS - L - 0486-13		MRS - L - 0469-13	MRS - I - 0468-13		MRS-L-0445-13		MRS-L-0434-13		MRS-L-0433-13		MRS - L - 0432-13
JACOBY GIBSON	STEPHANIE SHIFFLETT	STEPHANIE PERDUE and AARON PERDUE	AMANDA CHEREE LOYD	CASSIE MARIE BEYER	BRYTTANY WRIGHT	CACCAND A 244 DITT	CASSANDKA MAKIE BENNETT	ESIMERALDA MEDEL	MARQUEZ	AMY E. SMITH and HINTER SMITH	TANGEN P. DOMINGON	IAIVESHA D. KUBINSON and DEMARI ROBINSON	NELL SAAB		ROCHRATA BRADLEY		CAROL KIRKLAND	ADRIENNE BARNES		AUTUMN HARRIS		JESSICA R. COFFEY JONES	REBECCA RAGI.E		MEGAN MARIE BLOCK		HEATHER LEE BESELER	and MICHAEL BESELER	HEATHER HANSEN and	JEHF HANSEN	BRITNEY NICOLE BREWINGTON
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05/10/2013 16:39 8432169440 MOTLEY RICE LLC PAGE 18/20 Case 7:13-md-02434-CS-LMS Document 77 Filed 05/13/13 Page 17 of 20

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None	None	None	None	None	None	None	None	None	None	None	None	None	None	None	None		None	None	None	None
None	None	None	None	None	None	None	None	None	None	None	None	None	None	None	None		None	None	None	None
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A		N/A	N/A	N/A	N/A
Pending Decision of Motion for Coordination	Pending Decision of Motion for Coordination	Pending Decision of Motion	Pending Decision of Motion for Coordination	Pending Decision of Motion for Coordination	Pending Decision of Motion for Coordination	Pending Decision of Motion for Coordination	Pending Decision of Motion for Coordination	Pending Decision of Motion for Coordination	Pending Decision of Motion for Coordination	Pending Decision of Motion for Coordination	n of Motion	1 of Motion	of Motion	n of Motion	n of Motion		Pending Decision of Motion for Coordination	of Motion	of Motion	ı of Motion
N.J. Sup. Ct., Morris Ctv	N.J. Sup. Ct., Morris Ctv.	N.J. Sup. Ct., Morris Cry	N.J. Sup. Ct., Morris Civ.	N.J. Sup. Ct., Morris Cty.	N.J. Sup. Ct., Morris Ctv.	N.J. Sup. Ct., Morris Ctv.	N.J. Sup. Ct., Morris Cty.	N.J. Sup. Ct., Morris Cty.	N.J. Sup. Ct., Morris Ctv.	N.J. Sup. Ct., Morris Ctv.	N.J. Sup. Ct., Morris Cty.	N.J. Sup. Ct., Morris Cty.	N.J. Sup. Ct., Morris Ctv.	N.J. Sup. Ct., Morris Ctv.	N.J. Sup. Ct., Morris Cty.		N.J. Sup. Ct., Morris Ctv.	N.J. Sup. Ct., Morris Ctv.	N.J. Sup. Ct., Morris Ctv.	N.J. Sup. Ct. Morris Cty.
MRS • L • 0396-13	MRS - L - 0373-13	MRS - L - 0372-13	MRS-L-0371-13	MRS - L - 0312-13	MRS-L-0274-13	MRS-L-0273-13	MRS - L - 0272-13	MRS - L - 0271-13	MRS - L - 0236-13	MRS-L-0222-13	MRS-L-0171-13	MRS-L-0170-13	MRS-L-0161-13	MRS-L-0125-13	MRS-L-0119-13		MRS - L - 0062-13	MRS - L - 0060-13	MRS - L - 0041-13	MRS - L - 0040-13
CROMER et al.	ARIANE DUBERRY	YOLANDA PARKER	CARRIE SMITH and JASON L. SMITH	BRITTANY WILLIAMS MCCLAIN and MICHAEL MCCLAIN	MASHELL FERRIS	AMBROCIA CASTANEDA	MARQUISHA ELMORE and DUPREE ELMORE	CARMEN SALINAS	ALEJANDRINA ORTIZ and PAFAEL ORTIZ	TYRA BEAVER and KEVIN BEAVER	BRENDA TILLET	TARRIN THOMAS	REEM ABDUL FATTAH	GALE WETZLER	BRIANA MORIAN and	TKEE MORIAIV	KRISTINE RENE BRUMFIELD ORMAN	AMANDA KAY ROSS and DENNIS WILLIAM ROSS	JADA RAE BELL and RYAN BELL	CARMEN OLIVIA LOPEZ
75	92	11	78	79	08	81	82	83	84	85	98	87	88	86	06		91	65	93	94

05/10/2013 16:39 8432169440 MOTLEY RICE LLC PAGE 19/20 Case 7:13-md-02434-CS-LMS Document 77 Filed 05/13/13 Page 18 of 20

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None	None	None	None		None	•	None		None	~~	None		None	;	None	None		None															
N/A	N/A	N/A	N/A		N/A		N/A		N/A	•	N/A		N/A	•	N/A	•	N/A		N/A		N/A		N/A		N/A		N/A		N/A	N/A		N/A	
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N.J. Sup. Ct., Morris Ctv	N.J. Sup. Ct.	N.J. Sup. Ct.,	N.J. Sup. Ct.	Bergen Cty.	N.J. Sup. Ct.,	Bergen Cty.	N.J. Sup. Ct.	Bergen Cty.	N.J. Sup. Ct.,	Bergen Cty.	Unknown		Unknown		Unknown		Unknown		Unknown		Unknown	Inbrasia	CLEARCOVIL	Unknown		Unknown							
MRS - L - 0038-13	MRS-L-0037-13	BER - L - 2732-13	BER - L - 2372-13		BER-L-2342-13		BER-L-2270-13		BER - L - 2226-13		BER - L - 2137-13		BER - L - 2116-13		BER - L - 1605-13		Unknown		Unknown		Unknown		Unknown		Unknown	111.01	Unknown	Inknown	THOUSE THE	Unknown		Unknown	
MELISSA ANN JARAMILLO	YARNELL LINETTE BATES	BETH EVANS	SHARON MAYHEW		DAKLENE LAURENCIN	אונינוגיה מונוגר	AMBER CONDIFF		KASSIE PEREZ		GINA FRANO		SHARON M. BLUE		TAMMY DELEON		BRIANNE ANDERSON-	HAKKIS	TYANNA DODSON		MAKLENA HAMILTON		KATKINA HERRON	A 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4	CLAUDIA JEZIORU	THE TANK RECORDER	LIBBAN MCGUIRE	KIMBERLY THOMPSON		BRENDA TILLETT		NICOLE TOLIVER, et al.	
95	96	26	86	1	<u> </u>	400	oor	1	101		102		103		104	1	105	+	106		107	4	801	200	501 1	110		111		112		113	

05/10/2013 15:39 8432169440 MOTLEY RICE LLC PAGE 20/20 Case 7:13-md-02434-CS-LMS Document 77 Filed 05/13/13 Page 19 of 20

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	None	None	None	None		Motion to Compel pending	基準	PENDING '	None	e e e	None
	None	None	Plaintiff has responded to interrogatories and request for production from co-defendants	None		Written discovery exchanged; plaintiff deposed		DISCOVERY TAKEN	None		None
7	N/A	N/A	N/A	N/A		N/A	· · · · · · · · · · · · · · · · · · ·	TRANSFERRED TO MDL	N/A	· · · · · · · · · · · · · · · · · · ·	N/A
					Service Servic		AGTIONS	STATUS		VEHONNE P	
ATTE COUNTY	Active	Active	Active	Active	ENITO THLE	Active	CATECOURT	.	Active	FATEGORET	Active
MISSOURISTATE GOURTACTIONS	Mo. Cir. Ct.	Mo. Cir. Ct.	Mo. Gir. Ct.	Mo. Cir. Ct.	NEW YORK TATEROUNE ACTIONS	Sup.Ct., New York County	CMITORVIES	COURT	Cal. Sup. Ct.	AMISSISSIPPISEATEGOIRE	Miss. Cir. Ct.
	1322-CC00276	1322-CC00276	Unknown	Unknown	多數是是	100482/2011		INDEX NO.	Unknown		Unknown
	KEISHA ALLEN et al.	LISA COLLINS et al.	STEPHANIE FAIRBRASS	JESSICA STOKER		CELINE WINANS, JON WINANS, HEATHER WILLIS AND RYAN WILLIS		CASE NAME	DESIREE INIGUEZ, et al.		CHASITY DANIELS
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FAX



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28 BRIDGESIDE BOULEVARD MOUNT PLEASANT, SC 29464 TEL: 843-216-9616 FAX: 843-216-9430	
Date: Friday, May 10, 2013 To: Honorable Cathy Seibel, USDJ Fax: 914-390-4278 Sender: Staci Palmer Barra for Carmen S. Scott, Esq. Client No.: 524057 The original will be mailed emailed to you.	
You should receive <u>20</u> pages, including this cover sheet. If you do not receive all the pages, please call 843-216-9000.	

Message:	

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